

REMARKS/ARGUMENTS

The above-identified patent application has been reviewed in light of the Examiner's Action dated July 9, 2009. Claims 1-17 have been amended, without intending to abandon or to dedicate to the public any patentable subject matter. No claims have been canceled by this paper. Claims 18-20 are new. Accordingly, Claims 1-20 are now pending. As set forth herein, reconsideration and withdrawal of the rejections of the claims are respectfully requested.

Claim 14 stands rejected under 35 U.S.C. §112 on the grounds that an included term lacks antecedent basis. In the amendments set forth above, Claim 14 has been amended to ensure proper antecedent basis for all of the included terms. Accordingly, it is submitted that the rejection of Claim 14 under 35 U.S.C. §112 should be reconsidered and withdrawn.

Claims 1-5 and 9 stand rejected under 35 U.S.C. §102 as being anticipated by or, in the alternative, under 35 U.S.C. §103 as obvious over U.S. Patent No. RE 34,753 to Groiso ("Groiso"). In addition, Claim 10 stands rejected under 35 U.S.C. §103 as being unpatentable over Groiso in view of U.S. Patent No. 6,725,118 to Fried et al. ("Fried"), Claims 6-8, 11, 13 and 15-17 stand rejected under 35 U.S.C. §103 as being obvious over Groiso in view of U.S. Patent No. 6,910,485 to Faries et al. ("Faries"), and Claims 12 and 14 stand rejected under 35 U.S.C. §103 as being obvious over Groiso in view of U.S. Patent No. 5,769,089 to Hand et al. ("Hand"). Anticipation under 35 U.S.C. §102 requires that the reference teach every aspect of the claimed invention either explicitly or impliedly. (*See* MPEP §706.02.) "[U]nless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed, and, thus, cannot anticipate under 35 U.S.C. §102." (*Net Moneyin, Inc. v. Verisign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008); 88 U.S.P.Q.2d 1751, 1759 (2008)). To establish a *prima facie* case of obviousness, all claim limitations must first be taught or suggested by the prior art. *See, e.g., DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1360 (Fed. Cir. 2006); 80 U.S.P.Q.2d 1641, 1645 (2006). "All words in a claim must be considered in judging the patentability of that claim against the prior art." MPEP § 2143.03 (citing *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA

1970)). The Examiner must then provide an explicit analysis of the motivation for combining the references. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007); 82 U.S.P.Q.2d 1385, 1396 (2007) ("a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art . . . ."). While the Examiner can choose one of several exemplary rationales from the MPEP to support an obviousness rejection, all the rationales in the MPEP still require the Examiner to demonstrate that all the claim elements are shown in the prior art. *See* MPEP § 2143, Original Eighth Edition, August 2001, Latest Revision July 2008. However, the cited references, whether taken alone or in combination, do not disclose each and every element of the pending claims. Accordingly, reconsideration and withdrawal of the rejections of the claims are respectfully requested.

Embodiments of the claimed invention are generally directed to a method or kit including a medical device, a bag for housing liquid, and a removal member. More particularly, the medical device is in contact with a removal member. The removal member that is in contact with the medical device and the removal member also extends from or is positioned outwardly of the bag for holding liquid, at least while heating the medical device. In use, the medical device is heated while the medical device is within the bag, while a first portion of the removal member is positioned about the medical device, and while a second portion of the removal member is positioned outwardly of the bag.

The Groiso reference is generally directed to an orthopedic rigid splint plate orthosis. More particularly, Groiso discusses a sterilized splint that is provided in a bag. Moreover, the splint is heated while still inside the bag. (Groiso, col. 2, ll. 49-58.) According to Groiso, prior to application, the bag containing the splint is cut open at one end and hot fluid is poured in to soften the splint plate, or an unopened bag may be submerged in hot fluid. (Groiso, col. 3, ll. 27-41; col. 4, ll. 58-63; col. 5, ll. 27-33.) The Office Action acknowledges that Groiso does not explicitly disclose a removal member for removing the medical device from the bag. For such disclosure, the Office Action states that it is obvious and well known in the art that tongs or other grasping utensils are used to pull the medical device out of the boiling water. In addition, the Office Action states that a portion of the removal member would be inside the bag grasping the medical device and a portion would

be outside the bag in the hands of the user. However, neither Groiso nor the assertion of the obviousness of the use of tongs contained in the Office Action discloses heating the medical device while the liquid, the medical device and at least a portion of the removal member are in the bag and while a first end of the bag is open, as generally recited by amended Claim 1. It also has not been demonstrated that a heating unit for heating the medical device while the medical device is within the bag, while the removal member is positioned about the medical device, while at least a first portion of the removal member is located within the bag, and while at least a second portion of the removal member is outward of the bag, as recited by Claim 11 are disclosed by the prior art. Therefore, the rejections of the claims as anticipated by or obvious in view of Groiso should be reconsidered and withdrawn.

In addition, Applicant notes that the bare statement that it is obvious and well known in the art to use tongs or other grasping utensils, without citation to prior art, is improper. Accordingly, the rejections of the claims in view of this unsupported finding should be reconsidered and withdrawn.

The Office Action acknowledges that the Groiso reference does not disclose holes that are formed using a laser. For such disclosure, the Fried reference is cited. More particularly, the portion of the Fried reference cited by the Office Action states that a laser can be used to cut a desired pattern on a disposable mold that is then used to prepare the needed splint. (Fried, col. 5, ll. 17-19.) However, forming holes in a mold is different than forming holes using a laser to cut holes in the splint material as required by amended Claim 10. Moreover, the Fried reference does not make up for other deficiencies in the disclosure of Groiso, for example with respect to the elements of Claim 1, from which Claim 10 depends. Accordingly, for at least these reasons, the rejections of Claim 10 should be reconsidered and withdrawn.

The Office Action acknowledges that Groiso does not explicitly disclose a heating unit. For such disclosure, the Office Action cites to the Faries reference. In general, Faries discusses a thermal treatment system with a recessed basin. More particularly, Faries discusses thermally treating sterile surgical liquids. However, Faries does not make up for the deficiencies in the disclosure of Groiso with respect to elements of the claims not generally directed to heating and medical device or a heating unit. Therefore, for at least

these reasons, the rejections of Claims 6-8, 11, 13 and 15-17 should be reconsidered and withdrawn.

The Hand reference is cited for disclosure of a nasal splint comprising an adhesive layer and a wrap. Generally, the Hand reference is directed to an external nasal splint. More particularly, the splint includes a sheet of flexible material that is joined to an adhesive layer. However, there is no disclosure in Hand of other aspects of the claims, such as a removal member positioned about a medical device, bag for housing liquid, or heating unit. Accordingly, for at least these reasons, the rejections of Claims 12 and 14 as obvious should be reconsidered and withdrawn.


Claims 18-20 are new and recite additional patentable subject matter. For example, Claim 18 depends from Claim 1 and specifies that the removal member comprises a folded sheet. As a further example, Claim 19, which depends from Claim 18, specifies that the folded sheet has a width that is less than the width of the bag and a length that is greater than the height of the bag. Claim 20 depends from Claim 11, and recites that the removal member comprises a folded sheet. As there is no teaching, suggestion or disclosure of such elements in the cited references, it is submitted that dependent Claims 18-20 are in condition for allowance.

The application now appearing to be in form for allowance, early notification of same is respectfully requested. The Examiner is invited to contact the undersigned by telephone if doing so would be of assistance.

Respectfully submitted,

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